

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/008521

International filing date (day/month/year)
29.07.2004

Priority date (day/month/year)
31.07.2003

International Patent Classification (IPC) or both national classification and IPC
C12N15/82

Applicant
GREENOVATION BIOTECH GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational Application No.
PCT/EP2004/008521

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/008521

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-16
Industrial applicability (IA)	Yes: Claims	1-16
	No: Claims	

2. Citations and explanations

see separate sheet

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)

International application No.

PCT/EP2004/008521

IP20 Rec'd PCT/PTO 31 JAN 2006

Re Item IV.

The separate inventions/groups of inventions are:

1. They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:
2. The following document/s (D) is/are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US 2003/113921 Article 123(2) EPC (STAUB JEFFREY M ET AL) 19 June 2003 (2003-06-19)
D2: SCHAEFER DIDIER G: "A new moss genetics: Targeted mutagenesis in Physcomitrella patens" ANNUAL REVIEW OF PLANT PHYSIOLOGY AND PLANT MOLECULAR BIOLOGY, ANNUAL REVIEWS INC, XX, vol. 53, 2002, pages 477-501, XP002233936 ISSN: 1040-2519
3. The International Preliminary Examination Authority (IPEA) agrees with the objection put forward by the International Searching Authority (ISA) as to lack of unity (Article 34(3) and Rule 13 PCT)
4. The international search report has been drawn up in respect of the entire international application, but the IPEA finds that the application does not comply with the requirement of unity of invention (Article 34(3) and Rule 13 PCT).
5. An international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship between the inventions involving one or more of the same or corresponding special technical features, special technical features being such features, that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The presently claimed subject-matter does not fulfil the above requirements on unity of invention: In view of the closest prior art (D1) and the description, the problem underlying the present application is the following: "Provision of

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alternative DNA construct, comprising a heterologous DNA sequence, which is embedded by recombination sequences."

6. The solution to this problem is however state of the art (see D1, Fig 7, Fig. 8, p. 1 paragraph 0003, 0005 and claims). the provision of proteins isolated from a plant source, having antifungal activity. However, this relation cannot be accepted to consist of special technical feature as defined above since it does not define a contribution which each of the different claimed inventions, considered as a whole makes over the prior art.
Thus, this feature cannot be accepted as a special technical feature as required by Rule 13 PCT.
7. Consequently, the technical relationship of the independent claims does not embrace a special technical feature, within the meaning of Rule 13.2 PCT. The following inventions have to be considered separately:
 - A. Method of amplifying gene expression in moss (Claims 1-8)
 - B. DNA construct comprising a heterologous DNA sequence flanked on the 5' end by a first recombination sequence and on the 3' end on a second recombination sequence (Claims 9 and partially claims 11-18).
 - C. DNA construct comprising a heterologous DNA sequence flanked on the 5' end by a second recombination sequence and on the 3' end on a first recombination sequence (Claims 10 and partially claims 12-18.)

The technical contributions of these groups of claims are different and are not directly linked or corresponding so that they could be considered to contribute a special technical feature as defined in Rule 13 PCT. Hence, the application lacks unity under Article 34(3) PCT in the light of Rule 13.2 PCT.

The Applicant may want to restrict the claims. If they were restricted to any of the above two indicated inventions, they would then comply with the requirements of unity of invention.

Re Item V.

8. The subject-matter of present claims 1-16 is new (Article 33(3) PCT).
9. The present application does not satisfy the criterion set forth in Article 33(3) PCT

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because the subject-matter of **claims 1-16** does not involve an inventive step. D1 is considered to represent the closest prior art and discloses specific constructs for improved plastid transformation via homologous recombination in moss.

The difference between D1 and the subject matter of **claims 1-16** of the present application is the utilisation of two different construct comprising recombination sequences, for amplifying gene expression.

Starting from D1, the underlying technical problem is whether the expression of heterologous nucleic acids which are transformed in two different construct embedded by recombination sequences are amplified.

The subject-matter of the claims referred to above is not considered to solve this requirement over the entire breadth. According to the problem solution approach, the technical problem has to be solved about the entire scope of claim. However in the present case it is not credible that any flanking sequence is able to amplify the expression of a heterologous DNA in moss. Consequently, **claims 1-16** do not fulfil the requirements of Article 33(3) PCT.

10. The terms "first-" or "second heterologous nucleic acid construct" (e.g. **claim 1**) renders the scope of said claim unclear, because the structure of the first and second heterologous nucleic acid construct is not defined (Article 6 PCT).

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